

1022114

**ELMSTech**, INC.

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11590, USA  
TEL: (516) 338 9888  
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SEP 17 2002

20 JUN 2002

**510(k) Summary**

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

***1. Applicant***

ELMSTECH, INC.  
950 JERICHO TURNPIKE  
WESTBURY, NEW YORK  
11590, USA

TEL: (516) 338 9888  
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CONTACT PERSON: ROBERT MANNERS  
PRESIDENT

***2. Device Identification***

<b>Proprietary Device Name:</b>	IMPERIUM MOBILE C-ARM X-RAY EQUIPMENT
<b>Common/Generic Device Name:</b>	MOBILE C-ARM X-RAY EQUIPMENT
<b>Classification Name:</b>	SYSTEM, X-RAY, MOBILE
<b>Product Code:</b>	IZL + JAA
<b>Regulatory Class:</b>	Class II
<b>Regulation Number:</b>	21 CFR 892.1720 + 892.1650

### 3. *Substantial Equivalence*

The **IMPERIUM MOBILE C-ARM X-RAY EQUIPMENT** is substantially equivalent to the following currently marketed devices:

- GE OEC 9800 PLUS (K021049)
- SIEMENS MEDICAL SIREMOBIL ISO-C (K973598)

### 4. *Description of Device*

The **IMPERIUM** is a mobile c-arm x-ray imaging equipment consisting of a c-arm stand and a monitor trolley. The c-arm stand holds the high-frequency x-ray generator, x-ray tube assembly, x-ray controls, image intensifier and TV camera. Monitor trolley supports the image display monitors, image processing and recording devices.

The **IMPERIUM** is designed to provide the user with smooth linear and rotational movements around patient without need of further reorientations. The C-arm movements are fully motorized for ease of operation.

The **IMPERIUM** is designed according to such principles as lower dosage, better image quality and manipulation, workflow enhancement, operator and patient comfort and versatility. The **IMPERIUM** can be operated at Fluoroscopy, Pulsed Fluoroscopy, Digital Radiography, Cassette Radiography, Digital Subtraction Angiography (DSA) and Roadmap modes. Image processing and storage capabilities such as last image hold, recursive filtering, real time edge enhancement, real time zooming, image reversal, continuous image rotation, radiation-free collimation and contrast/brightness adjustment are possible under user control.

### 5. *Intended Use*

The **IMPERIUM** is intended to provide fluoroscopic and radiographic imaging of the patient during diagnostic, surgical and interventional procedures. Clinical applications may include but are not limited to digital subtraction angiography (DSA), orthopedic, neurologic, abdominal, vascular, cardiac, critical care and emergency room procedures. The system may be used for other imaging applications at physician's discretion.

### 6. *Technological Characteristics*

The **IMPERIUM** employs the same technological characteristics as the predicate devices. This device is intended for the same applications as the currently

marketed predicate devices. All systems are image intensified mobile c-arm x-ray imaging systems with fluoroscopic and cassette exposure capabilities. Like the predicate devices, **IMPERIUM** consists of a c-arm stand, and standard system components: x-ray generator, x-ray tube, Image Intensifier, TV system and a monitor trolley.

The **IMPERIUM** is designed to give the best movement controls to the operator for quick and accurate imaging of the patient in order to save the dose and time. The orbital movement range of c-arm is 190°. The horizontal travel range is 20 cm and vertical travel range is 40 cm. The horizontal swivel range is  $\pm 12.5^\circ$ . A large c-arm depth of 78 cm provides the user with comfortable patient access for the examinations. The image intensifier can be moved in up/down direction independently up to 20 cm to have less source-to-image intensifier distance. With this feature user can concentrate better on a specific region of interest while decreasing the dose applied and getting a better image quality.

- Isocentric C-arm
- Wide Orbital Angle range of 190°
- Large x-ray tube to image intensifier distance of 78 cm
- Independent source to image intensifier distance adjustment of 20 cm
- Fully motorized movements

## 7. Standards

The **IMPERIUM** is designed in accordance with the national and international product safety and performance requirements established in the following standards given in Table-1:

21 CFR 1020.30-32	FEDERAL PERFORMANCE STANDARD FOR DIAGNOSTIC X-RAY SYSTEMS
ANSI/NFPA 70&99	NATIONAL ELECTRICAL CODE and STANDARD for HEALTHCARE FACILITIES
UL 2601	MEDICAL ELECTRICAL EQUIPMENT
CSA-C22.2 No. 601.1-M90	MEDICAL ELECTRICAL EQUIPMENT
IEC 60601-1-1	Medical Electrical Equipment-Part 1 General Requirements for Safety” with Ammend 1 and 2
IEC 60601-1-2	Medical Electrical Equipment-Part 1 General Requirements for Safety-2. Collateral Standard: Electromagnetic Compatibility-Requirements and Tests

IEC 60601-1-3	Medical Electrical Equipment-Part 1 General Requirements for Safety-3. Collateral Standard: General Requirements for radiation protection in diagnostic x-ray equipment
IEC 60601-2-7	Medical Electrical Equipment-Part 2 Particular Requirements for the Safety of high-voltage generators of diagnostic x-ray generators
IEC 60601-2-28	Medical Electrical Equipment, X-Ray Tubes and X-Ray Source Assemblies
IEC 60601-2-32	Medical Electrical Equipment-Part 2 Particular Requirements for the Safety of associated equipment of x-ray equipment

Table-1 Product Performance and Safety Standards

Results of performance and compliance testing conducted at manufacturing facility and independent test organizations on **IMPERIUM** system, indicates conformance to all applicable performance standards promulgated by FDA for these systems.

#### 8. *Conclusion*

Based on the comparison to other devices in technological characteristics and intended use, the **IMPERIUM** c-arm mobile x-ray imaging system is substantially equivalent to the predicate devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 17 2002

ELMSTech, Inc.  
% Mr. Tim Mangeruga  
Legal Assistant  
Manners & Associates, P.C.  
950 Jericho Turnpike, Suite 100  
WESTBURY NY 11590-1597

Re: K022114  
Trade/Device Name: Imperium Mobil C-arm  
X-Ray System  
Regulation Number: 21 CFR 892.1650  
Regulation Name: Image-intensified fluoroscopic  
x-ray system  
Regulation Number: 21 CFR 892.1720  
Regulation Name: Mobil x-ray system  
Regulatory Class: II  
Product Code: 90 JAA and IZL  
Dated: June 21, 2002  
Received: June 28, 2002

Dear Mr. Mangeruga:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

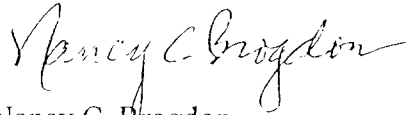
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## STATEMENT OF INDICATIONS FOR USE

**Applicant:** ELMSTECH, INC.

950 JERICHO TURNPIKE  
WESTBURY, NEW YORK  
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PHONE: (516) 338-9888  
FAX: (516) 338-9889

**510(k) NUMBER:** K022114

**DEVICE NAME:** IMPERIUM MOBILE C-ARM X-RAY IMAGING  
EQUIPMENT

### INDICATIONS FOR USE:

The **IMPERIUM** is intended to provide fluoroscopic and radiographic imaging of the patient during diagnostic, surgical and interventional procedures. Clinical applications may include but are not limited to digital subtraction angiography (DSA), orthopedic, neurologic, abdominal, vascular, cardiac, critical care and emergency room procedures. The system may be used for other imaging applications at physician's discretion.

*Prescription Use* ✓

David A. Segman  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K022114